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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,696	11/25/2003	Eleni Venetsanakos	18835.002	3048

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,696	VENETSANAKOS, ELENI	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Venetsanakos

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 2, drawn to a method of claim 1, wherein said at least one Porimin binding partner comprises a polypeptide, classified in class 514, subclass 2.

II. Claims 3-8, drawn to a method of claim 1, wherein said at least one Porimin binding partner comprises an immunoglobulin or a functional equivalent thereof, classified in class 424, subclass 130.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claims 5 and 6 (i.e. SEQ ID Nos. 5 and 6). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

III. Claims 9 and 10, drawn to a method of claim 1, wherein said at least one Porimin binding partner comprises a polynucleotide Porimin binding partner, classified in class 514, subclass 44.

IV. Claim 11, drawn to a method of claim 1, wherein said at least one Porimin binding partner comprises a small molecule, classified in class 424, subclass 600, for example.

V. Claims 20 and 31, drawn to a Porimin binding partner, a pharmaceutical composition comprising Porimin binding partner, wherein said Porimin binding partner comprises a polypeptide, classified in class 530, subclass 350.

VI. Claims 21-26 and 32-37, drawn to a Porimin binding partner, a pharmaceutical composition comprising Porimin binding partner, wherein said Porimin binding partner comprises an immunoglobulin or a functional equivalent thereof, classified in class 530, subclass 387.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claims 25, 36 and 37 (i.e. SEQ ID Nos. 5 and 6). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

VII. Claims 27-28 and 38-39, drawn to a Porimin binding partner, a pharmaceutical composition comprising Porimin binding partner, wherein said Porimin binding partner comprises a polynucleotide, classified in class 536, subclass 23.1.

VIII. Claim 29 and 40, drawn to a Porimin binding partner, a pharmaceutical composition comprising Porimin binding partner, wherein said Porimin binding partner comprises a small molecule, classified in class 585, subclass 1, for example.

IX. Claim 43, drawn to a microarray comprising one or more polynucleotide sequences, classified in class 536, subclass 24.3.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a species from SEQ ID NOS 1 and 2 (see paragraph 5 below).

X. Claims 44 and 45, drawn to a method of determining the presence or absence of a cancer, a patient's predisposition to a cancer using the microarray of claim 43, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a species SEQ ID NOS 1 and 2 (see paragraph 5 below).

XI. Claims 46, drawn to a microarray comprising one or more protein-capture agents that bind one or more amino acid sequences, classified in class 530, subclass 387.1.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a species from SEQ ID NOS 3-6 (see paragraph 5 below).

XII. Claims 47-48, drawn to a method of determining the presence or absence of a cancer, a patient's predisposition to a cancer using the microarray of claim 46, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a species from SEQ ID NOS 3-6 (see paragraph 5 below).

XIII. Claims 49-53, drawn to a method of screening for a Porimin binding partner using a cell line transfected with an expression vector, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claim 51 (i.e. SEQ ID Nos. 1 and 2). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

XIV. Claims 54-57, drawn to a method of screening for a Porimin binding partner using membranes isolated from a cultured cell line transfected with an expression vector, classified in class 435, subclass 7.2.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claim 55 (i.e. SEQ ID Nos. 1 and 2). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

XV. Claims 58-63, drawn to a method of screening for a Porimin binding partner using the extracellular domain of Porimin, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claim 59 (i.e. SEQ ID Nos. 1 and 2). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

XVI. Claim 64-66, drawn to a method of screening a candidate-binding partner of Porimin using a cancer cell, classified in class 435, subclass 7.23.

XVII. Claims 67-73, drawn to a method of determining the ability of a drug to inhibit ligand binding to Porimin using a cell line transfected with an expression vector, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claim 68 (i.e. SEQ ID Nos. 1 and 2). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

XVIII. Claims 74-80, drawn to a method of determining the ability of a drug to inhibit ligand binding to Porimin using membranes isolated from a cultured

cell line transfected with an expression vector, classified in class 435, subclass 7.2.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from Claim 76 (i.e. SEQ ID Nos. 1 and 2). This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NO is structurally and functionally distinct molecule that would require separate search.

2. Claims 1 and 12-18 are linking claims that link groups I-IV. Claims 19 and 30 are linking claims that link groups V-VIII. Claims 41 and 42 are linking claims that link groups X and XII. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP j 804.01.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV, X, and XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. A method of treating or preventing a cancer (groups I-IV), a method of determining the presence or absence of a cancer (groups X and XII), a method of screening for a Porimin binding partner (groups XIII-XVI) and a method of determining the ability of a drug to inhibit ligand binding to Porimin (groups XVII and XVIII), are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material and comprises different methodological steps. For groups I-IV, a Porimin binding partner is administered to a cancer patient, for groups X and XII, the level of Porimin expression in a patient biological sample is detected and used to diagnose a cancer in said patient, for groups XIII-XVI, a Porimin binding partner is screened and identified, and for groups XVII and XVII, a drug which can inhibit ligand binding to Porimin is screened. Therefore, the methods of groups I-IV, X, and XII-XVIII are patentably distinct.

The inventions of groups I-IV further differ from each other in that the material used in these methods is different. For inventions of I, a polypeptide is used, for inventions of groups II, an antibody is used; for inventions of group III, a polynucleotide is used, and for inventions of groups IV, a small molecule is used. Moreover,

inventions of groups X and XII further differ from each other in that the material used in these methods is different. For inventions of groups X, a microarray comprising polynucleotide is used, for inventions of groups XII, a microarray comprising protein-capture agents are used. The inventions of groups XIII-XVI further differ from each other in that the material used in these methods is different. For group XIII, a cell line transfected with an expression vector is used, for group XIV, cell membranes are used, for group XV, the extracellular domain of Porimin is used, and for groups XVI, a cancer cell is used. The inventions of groups XVII and XVIII further differ from each other in that the material used in these methods is different, for group XVII, a cell line transfected with an expression vector is used, and for group XVIII, cell membranes are used. For these reasons, the inventions of groups I-IV, X, and XII-XVIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of group I-IV, X, and XII-XVIII together.

Groups V-VIII, IX and XII are drawn to patentably distinct products, wherein each has a different structure and function, which require separate searches, and wherein each is capable of separate manufacture and use.

Groups I & V, II & VI, III & VII, IV & VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to generate antibodies, the antibody can be used to detect a protein, the polynucleotide can be used to make a protein, and the small molecule can be used as a protein inhibitor as opposed to being used in the method of treating or preventing a cancer.

Searching the inventions of groups I & V, II & VI, III & VII, IV & VIII together would impose serious search burden. The inventions of groups I & V, II & VI, III & VII, IV & VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the products and the methods of using the product for treating cancer are not coextensive. The search for groups V-VIII would require a text search for the method steps. Prior art which teaches a product would not necessarily be applicable to the method of using the product. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Groups IX and X, XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the cancer can be detected by imaging as opposed to being detected by microarray.

Searching the inventions of groups XI and X, XI and XII together would impose serious search burden. The inventions of groups XI and X, XI and XII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the products and the methods of using the product for detecting a cancer are not coextensive. The search for groups X and XII would require a text search for the method steps. Prior art which teaches a product would not necessarily be applicable to the method of using the product. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Any one of groups V-VIII and any one of groups X, and XII-XVIII are unrelated because the product of group V-VIII is not used or otherwise involved in the process of groups X, and XII-XVIII. Moreover, any one of groups IX and XI and any one of groups I-IV and XIII-XVIII are unrelated because the product of group IX and XI is not used or otherwise involved in the process of groups I-IV and XIII-XVIII.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species:

(i) colon cancer, prostate cancer, breast cancer, leukemia.

(ii) SEQ ID NO.1, SEQ ID NO.2

(iii) SEQ ID NO. 3, SEQ ID NO.4, SEQ ID NO.5 and SEQ ID NO.6.

The species are independent or distinct. Each cancer is distinct from the other because their distinct etiology and property. Different genes and/or proteins are overexpressed in different cancers. Different methods are used for diagnosing and treating different cancers. Therefore they are distinct. Each sequence is distinct from the other because each sequence is a structurally and functionally distinct molecule, which requires separate searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-11, 17-18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang
Art Unit 1643
May 23, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER